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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,751	12/21/2000	Mark N. Hochman	3486-018	1104
22440	7590	12/23/2003	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC 270 MADISON AVENUE 8TH FLOOR NEW YORK, NY 100160601			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3763	9

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/745,751

Applicant(s)

HOCHMAN, MARK N.

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 2, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by BROWN (U. S. Patent No. 3,244,172). Brown discloses that it is well known in the art to turn or twist a needle of a syringe while inserting it through tissue in methods of injecting. (1:15-23).

Claims 1, 3, 4, 7, 8, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by GARNIER (U. S. Patent No. 4,381,777). Garnier discloses oscillating a needle of a syringe along its longitudinal axial when performing an injection. A gear mechanism that returns the needle to its starting orientation performs the oscillations. See Figs. 4-5a.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over BROWN or GARNIER. Brown and Garnier disclose the claimed invention, but do not explicitly disclose a rotation angle of 0-180 degrees and needle advance rate of 2-4 mm/sec. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a rotation angle of 0-180 because 0 degrees is a conventional non-rotating injection. Use of other rotation angles and an advance rate of 2-4 mm/sec would be obvious to one of ordinary skill in the art as a design choice because Applicant has not stated that this angle of rotation or advance rate serves any particular purpose or solves any stated problem and it appears that other rotation angles and advance rates would function equally as well.

Response to Amendment

The declaration filed on 10/03/03 under 37 CFR 1.131 is sufficient to overcome the Smith ('064) reference.

Response to Arguments

Applicant argues that Brown does not disclose rotating and translating a needle simultaneously and that it is impossible to jab and rotate simultaneously. The examiner disagrees and maintains that Brown discloses rotation to enter tissue (i.e., advancement) to make it easier for the needle to enter the tissue. Applicant does not supply any reasoning why it would be impossible to jab and rotate simultaneously. Furthermore, Brown teaches that jabbing is the

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usual procedure, but that turning or twisting may be employed at some times to get an easier entry, clearing drawing a distinction between the jabbing procedure and the twisting procedure.

Applicant states that there is nothing in Garnier about translating a needle with simultaneous rotation. The examiner disagrees. Garnier is concerned with perforating the osseous cortex in order to access porous bone underneath for administering a drug. In order to perforate (i.e., advance into) this hard shell Garnier teaches to rotate the needle. The act of perforating requires advancement of the needle.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. VILLETTE (U. S. Patent No. 4,787,893) describes a method of advancing a needle with simultaneous rotation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh
20 December 2003

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
PRIMARY EXAMINER